REMARKS

Introductory Remarks

Claims 1, 3-16, 19-26, 29-52, 54, 56, and 58-67 are pending in the application. Claims 33-37 and 46 have been previously withdrawn. Claims 2, 17, 18, 27, 28, 53, 55, and 57 have been canceled. Claims 1, 5, 6, 10-14, 26, 31, 38-41, 45, 48, 51, 56, and 58-61 have been amended. New claims 66 and 67 are added herein.

Applicants have amended claims 5, 6, 31, 40, 41, 45, 58, and 60 to correct inadvertent typographical and grammatical errors. The amendments to claims 5, 6, 31, 40, 41, 45, 58, and 60 are related to form and grammar only, and were made only for the purpose of improving the clarity of the claims. No new matter has been added by amendments of claims 5, 6, 31, 40, 41, 45, 58, and 60.

New claim 66 is directed to an isolated nucleic acid encoding a polypeptide, wherein the nucleic acid comprises a polynucleotide sequence that is at least 95% identical to a polynucleotide sequence as shown in SEQ ID NO:7, and wherein the polypeptide, when produced in a solanaceous plant, confers disease resistance in the plant, and wherein the polynucleotide comprises a detectable label. No new matter is added by this claim, which is supported by paragraphs 0072 and 0073 of the specification.

New claim 67 is directed to an isolated nucleic acid encoding a polypeptide, wherein the nucleic acid comprises a polynucleotide sequence that is at least 95% identical to a polynucleotide sequence as shown in SEQ ID NO:7, and wherein the polypeptide, when produced in a solanaceous plant, confers disease resistance in the plant, and wherein the polynucleotide comprises a label selected from the group consisting of an isotope, a chromophore, a lumiphore, a chromogen, or a biotin. No new matter is added by this claim, which is supported by paragraphs 0073 and 0163 of the specification.

Interview Summary

Applicants' attorney Stankovic conducted a telephonic interview with Examiner Ibrahim on March 13, 2007, in order to address outstanding rejections in the present application. In particular, issues related to the percentage sequence identity were discussed. The amendments contained in this paper are substantially as suggested by the Examiner, who is thanked for her consideration in this matter.

Claim Rejections - 35 U.S.C. §112, second paragraph

Claim 47 stands rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter of the invention. In particular, the Office action alleges that the recitation of "labeled" polynucleotide is unclear and is not defined in the specification.

Applicants respectfully disagree. At multiple places throughout the specification, Applicants describe what is meant by "labeled" polynucleotides and provide examples that teach the use of labeled polynucleotides. In the specification, Applicants refer to "labels" (*e.g.*, in paragraph 0072), disclose labeling of nucleic acid probes or oligonucleotides (*e.g.*, in paragraph 0073), labeled antibodies (*e.g.*, in paragraph 0015), and disclose ways of using labeled probes (*e.g.*, in paragraphs 0163, 0164). Accordingly, Applicants respectfully request that this rejection be withdrawn.

Claim Rejections - 35 U.S.C. §112, first paragraph

Enablement

Claims 1-3, 5-10, 12-15, 17-32, 38-40, 42-45, and 47-65 are rejected under 35 U.S.C. §112, first paragraph, for lack of enablement based on the Examiner's finding that the claimed invention does not provide enablement for sequences having at least 70% or 95% identity to the disclosed sequences. Claims 2, 17, 18, 27, 28, 53, 55, and 57 have been canceled and therefore the Examiner's rejection of these claims for lack of enablement has been overcome. Applicants have amended claims 1, 5, 6, 10, 12-14, 26, 31, 38-40, 45, 48, 51, 53, 56, and 58-61.

One of skill in the art will recognize that many polypeptides, encoded by specific nucleic acids, have specific crucial amino acids, or active sites, and therefore many nucleic acids, encoding non-crucial amino acids, can be changed in a polynucleotide or a polypeptide sequence without substantially altering the physiological function or activity of that polynucleotide or polypeptide, respectively. At pages 10, 11, 12, 23 and 24 of the instant specification, Applicants suggest substitutions of nucleic or amino acids that may be made in various sequences, yet still conserve the structure and function of the encoded wild-type polynucleotide and polypeptide. In paragraph 0050, Applicants disclose specific sections of preferred RB polynucleotides. Applicants submit that the skilled artisan would recognize that variants and fragments of SEQ ID NO:7 and SEQ ID NO:8 would have the same or at least similar utility to full length polynucleotides and polypeptides in conferring disease resistance. For example, the description of SEQ ID NO:4 at page 69 of the instant specification discloses "SEQ ID NO:4: Coding region of mutant disease resistant gene (cloned by PCR)". Thus, the specification teaches that mutant RB coding sequences can also provide disease resistance activity. SEQ ID NO:4 is at least 95% identical to SEQ ID NO:7.

Furthermore, *a considerable amount of experimentation is permissible*, if it is merely routine, or *if the specification provides a reasonable amount of guidance* with respect to the direction in which the experimentation should proceed. *See In re Wands,* 858 F. 2d 731, 737 (Fed. Cir. 1988)(emphasis added). Moreover, according to the MPEP § 2164.01, "the fact that experimentation may be complex does not necessarily make it undue, if the art typically engages in such experimentation."

In accord with the interview conducted with the Examiner, and further in accord with the USPTO Synopsys of Application of Written Description Guidelines, available at http://0-www.uspto.gov.mill1.sjlibrary.org/web/menu/written.pdf, claims to sequence variants with at least 95% identity to disclosed sequences, in combination with a stated functional limitation, are adequately described and are patentable. Applicants have amended claims such that the claimed variant and fragment nucleic acids, as well as polypeptides of the present invention, have at least 95% sequence identity to the

disclosed polynucleotide of SEQ ID NO:7 or the disclosed polypeptide of SEQ ID NO:8, respectively, as well as the ability to function in disease resistance in plants.

Claim 1 has been amended to clarify that the claimed nucleic acid comprises a polynucleotide sequence that is at least 95% identical to the polynucleotide sequence shown in SEQ ID NO:7, and that the polynucleotide sequence encodes a polypeptide that confers disease resistance in a solanaceous plant. The amendment of claim 1 is supported by paragraphs 0011 and 0091 of the specification.

Claim 10 has been amended to clarify that the claimed nucleic acid encodes a polypeptide comprising an amino acid sequence that is at least 95% identical to the amino acid sequence of SEQ ID NO:8, where the polypeptide, when produced in a plant, confers disease resistance in the plant. The amendment of claim 10 is supported by paragraphs 0011 and 0091 of the specification.

Claim 13 has been amended to clarify that the claimed recombinant expression cassette comprises a promoter sequence that is operably linked to a nucleic acid, where the nucleic acid comprises a polynucleotide sequence encoding a polypeptide comprising an amino acid sequence that is at least 95% identical to the amino acid sequence of SEQ ID NO:8, and where the polypeptide, when produced in a solanaceous plant, confers disease resistance in the plant. The amendment of claim 13 is supported by paragraphs 0011, 0091, and 0167 of the specification.

Claim 26 has been amended to clarify that the claimed transgenic solanaceous plant comprises a recombinant expression cassette comprising a promoter sequence operably linked to a nucleic acid encoding a RB polypeptide, where the nucleic acid comprises a polynucleotide sequence encoding a polypeptide comprising an amino acid sequence that is at least 95% identical to SEQ ID NO:8, and where the polypeptide, when produced in the plant, confers disease resistance in the plant. The amendment of claim 26 is supported by paragraphs 0022, 0029, 0096, 0107, and 0108 of the specification.

Claim 38 has been amended to clarify that the claimed method of enhancing disease resistance in a solanaceous plant comprises introducing a construct comprising a promoter operably linked to a nucleic acid encoding a polypeptide comprising an

amino acid sequence that is at least 95% identical to SEQ ID NO:8, and where the polypeptide, when produced in a plant, confers disease resistance in the plant. The amendment of claim 38 is supported by paragraphs 0023 and 0074 and by Example 4 of the specification.

Claim 48 has been amended to clarify that the claimed isolated nucleic acid comprises a polynucleotide sequence which hybridizes under stringent conditions to SEQ ID NO:7 or the complement thereof, where the hybridization reaction is incubated at 42°C in a solution comprising 50% formamide, 5x SSC, and 1% SDS or at 65°C in a solution comprising 5x SSC and 1% SDS, with a wash in 0.2x SSC and 0.1% SDS at 65°C, and where the nucleic acid encodes a polypeptide which, when produced in a solanaceous plant, confers disease resistance in the plant. The amendment of claim 48 is supported by paragraphs 0092 and 0093 of the specification.

The Examiner further contends that the specification is not enabling for promoter sequences other than the promoter sequence of SEQ ID NO:23. Applicants respectfully disagree. At pages 29-37 and 39-41 of the instant specification, Applicants disclose promoters. In one example at page 40, Applicants teach that a promoter sequence of the present invention can be identified by analyzing the 5', or in some instances 3', region of a genomic clone corresponding to the disease resistant genes with sequence described under GenBank Accession Number AY303170. In the GenBank database, the locus AY303170 is a complete sequence of *Solanum bulbocastanum* chromosome 8 clone UW3A14, which is 79178 bases long. Applicants submit that the skilled artisan would be able to analyze a 79 kb long sequence to identify promoter regions.

Claim 51 has been amended to clarify that the claimed isolated nucleic acid molecule for controlling expression of genes confers plant disease resistance in transformed plant cells, and that the isolated nucleic acid molecule comprises a segment of a RB gene from a plant species selected from the *Solanaceae* family, the RB gene comprising a coding sequence that is at least 95% identical to SEQ ID NO:7, the segment commencing at a location about 2,500 bases upstream from a transcription initiation site of the gene, and ending at a location about 250 bases downstream from

the transcription initiation site. The amendment of claim 51 is supported by paragraphs 0026, 0028, and 0048 of the specification.

Claim 56 has been amended to clarify that the claimed DNA segment for effecting expression of coding sequences operably linked to the segment, isolated from a RB gene whose coding region hybridizes under stringent conditions with a coding region defined by SEQ ID NO:7, comprises a promoter, a transcription initiation site, and an element that confers disease resistance on expression of the coding sequences. The amendment of claim 56 is supported by paragraphs 0019, 0028, 0092, and 0093 of the specification.

No new matter has been added by amendment of claims 1, 5, 6, 10, 12-14, 26, 31, 38-40, 45, 48, 51, 53, 56, and 58-61. Amended independent claims 1, 10, 13, 26, 38, 48, 51, and 56 are now patentable. Claims 3-9 depend from claim 1; claims 11 and 12 depend from claim 10; claims 14-16 and 19-25 depend from claim 13; claims 29-32 depend from claim 26; claims 39-45 depend from claim 38; claims 49 and 50 depend from claim 48; claims 52, 54, and 61-65 depend from claim 51; claims 58-60 depend from claim 56. Because independent claims 1, 10, 13, 26, 38, 48, 51, and 56 are now patentable, claims that are dependent from these claims are also patentable in view of the amendments and remarks pertaining to claims 1, 10, 13, 26, 38, 48, 51, and 56.

For all of these reasons, Applicants submit that enablement is commensurate with the scope of the claims 1, 5, 6, 10-14, 26, 31, 38-41, 45, 48, 51, 56, and 58-61. Applicants respectfully request that this ground of rejection be withdrawn.

Written Description

Claims 1-2, 5-10, 12-14, 17-32, 38-39, and 42-45 are rejected under 35 U.S.C. § 112, first paragraph for failure to satisfy the written description requirement. The Examiner alleges that claims 1-2, 5-10, 12-14, 17-32, 38-39, and 42-45 contain subject matter which is not described in the specification in such a way as to reasonable convey to one skilled in the art that the inventors, at the time of the application, had possession of the claimed invention. Claims 2, 17, 18, 27, and 28 have been canceled and therefore the Examiner's rejection of these claims for failure to satisfy the written

description requirement has been overcome. Applicants have amended claims 1, 5, 6, 10, 12-14, 26, 31, 38-40, 45, 48, 51, 53, 56, and 58-61. Applicants submit that amended claims 1, 5-10, 12-14, 19-32, 38-39, and 42-45 are adequately described in the present application. Applicants further submit that Applicants had possession of the claimed invention at the time of filing the application.

The factors to be considered in determining whether an adequate written description has been set forth include: (1) disclosure of complete or partial structure, (2) physical or chemical properties, (3) functional characteristics, (4) structure/function correlation, and (5) methods of making the claimed product or any combination thereof. *See Guidelines for Examination of Patent Applications Under the 35 U.S.C. § 112 "Written Description" Requirement,* 66 Fed. Reg. 1099, 1106 (Jan. 5, 2001). Applicants submit that the present application discloses a combination of the above elements required for an adequate written description and therefore sets forth an adequate written description of the claimed invention.

The structure and sequence of the wild type nucleic acid encoding RB, encompassed by the claims, are described throughout the specification. For example, at pages 42-56, the specification describes isolation of DNA or cDNA clones encoding the resistance genes of the present invention. Several structural features, such as open reading frames, domains, and motifs, are disclosed at pages 10-12 and 65. At pages 39-41, the specification teaches promoters of the present invention. At pages 37-39 and 57-58, the specification teaches plant transformation with the disease resistant genes of the present invention, and detection of transgenic plants of the present invention.

For at least the reasons pertaining to claim amendments stated above, Applicants submit that the specification recites distinguishing, identifying characteristics, sufficient to satisfy the written description requirement with respect to the claims. Applicants respectfully request the Examiner withdraw this ground of rejection.

SUMMARY

Applicants believe that currently pending claims 1, 3-16, 19-26, 29-52, 54, 56, and 58-67 are patentable. Applicants respectfully request the Examiner grant early allowance of this application. The Examiner is invited to contact the undersigned attorney for Applicants via telephone if such communication would expedite this application.

Respectfully submitted,

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